



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,933	10/04/2005	Amjad Ali	21150P	6475
210	7590	07/07/2009	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			LOEWE, SUN JAE Y	
		ART UNIT	PAPER NUMBER	
		1626		
		MAIL DATE		DELIVERY MODE
		07/07/2009		PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,933	ALI ET AL.	
	Examiner	Art Unit	
	SUN JAE Y. LOEWE	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 April 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 8-14 and 22 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 11-14 and 22 is/are allowed.
 6) Claim(s) 8-10 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Claims 8-14 and 22 are pending in the instant application.

Response to Arguments

2. Applicant's remarks have been fully considered. The 35 USC 103 rejection is withdrawn with respect to claim 22. The rejection is maintained with respect to claims 8-10. Below are responses to Applicant's remarks:

.. Here, the chemical art of the instant application is both unpredictable and vast. The Examiner's assertion that "[o]ne of ordinary skill would be motivated, from the prior art disclosure ... i.e. generic teaching and the preferred embodiment - to make the modification required to arrive at the instant invention" is simply unsupported by the teachings of the cited references. These references, either alone or in combination, fail to identify the Ali Compound as the lead compound for further modifications. Moreover, the references also fail to provide any suggestion or motivation to make the particular molecular modifications necessary to arrive at the Instant Compound from the Ali Compound.

.....
As a general matter, the Examiner's position that a skilled artisan would have been motivated to select the Ali Compound as the lead compound, reverse the reaction steps of Ali and modify the Ali Compound through the Homolog Compound in the particular way required to arrive at the Instant Compound is contrary to the teachings of the cited references.

.....
There is no disclosure whatsoever in the cited references that the synthetic intermediate or any of its homolog compounds possesses any selective glucocorticoid receptor activity. Additionally, a skilled artisan would have no reason to believe that the synthetic intermediate would have any activity since this compound has vastly different chemical structure than those of the active compounds disclosed in Ali.

.....
There is no teaching or suggestion in Ali that the Ali Compound possesses any superior property over the rest of the compounds and thus there would have been no reason or motivation to select this compound as the lead compound.

.....

Art Unit: 1626

Compound) to the Ali Compound. It does not in any way teach or suggest that the synthetic routes are reversible and does not disclose any routes or conditions for a reverse process. There also is no indication that the process of modifying the Ali Compound to the Instant Compound through the Homolog Compound was a routine process at the time of the instant invention. Therefore, a skilled artisan would not have known what synthetic routes and conditions to use to arrive at the Instant Compound from the Ali Compound. " "

Applicant's response is noted, however, it is not found to be persuasive. The prior art states that the compounds disclosed exhibited similar IC₅₀ values between 10 μM and 1 nM. Thus, one of ordinary skill would be motivated to choose any of the compounds disclosed as they are stated to have reasonably similar activity. The modification of the Ali compound to the homolog would necessarily produce a synthetic intermediate within the scope of the instant claims. Thus, notwithstanding activity of the synthetic intermediate towards the glucocorticoid receptor, it is maintained that this instantly claimed compound is obvious over the prior art. Furthermore, the prior art provides a generic synthetic route which needs not be modified to produce the "Instant Compound." The use of a different starting material, which is readily available, would lead to the synthesis "of the "Instant Compound."

Conclusion

3. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Golam M. M. Shameem/
Primary Examiner, Art Unit 1626

/Sun Jac Y. Loewe/
7-3-2009